K011411

P1/2

JUN 13 2001

510(k) Summary of Safety and Effectiveness

I. Trade Name: Sof-Pach™ TENS Electrode

Sponsor: Pain Management Technologies, Inc.
43 East Market St.
Akron, Ohio 43215
Registration No. Not yet assigned

Device Generic Name: Electrode Cutaneous

Classification: Class II
Product Code: 84gxy

Predicate Devices: The k915333 and the k912643 electrodes

II. Indications for use:
The PMT electrodes are intended to be used for tens and ems stimulation for pain relief.

III. Device/product Description: The Sof-Pach™ PMT electrodes are high quality pin-type electrodes. PMT electrodes are non-sterile self-adhering, Carbon Mesh, reposition able electrode, for use with a T.E.N.S. or E.M.S. devices.

IV. Contraindications, Warnings, and Precautions: Do Not Use Power 200 On Subjects With the Following Conditions:

1) Acute Disease
2) Infectious Disease
3) Malignant Tumors
4) Heart Disease
5) Feverish Disease
6) Pregnant Women
7) Skin Allergy
8) Abnormal Blood Pressure

This device should be used under the Supervision of a Physician. Never use a damaged electrode. Discontinue use if there is any irritation or any adverse effects present. Then contact your practitioner.

V. Alternative Practices and Procedures: N/A

VI. Marketing History: Refer to Attachment 1

VII. Potential Adverse Effects of the Device on Health: If the device is used improperly or for extended periods without replacement, then there is a Possibility for minor burns.

VIII. Summary of Pre-clinical Studies, Laboratory studies, Animal studies, and Additional studies: Refer to NAMSA Reports (Attachments 3,4,5)

IX. Summary of Clinical Studies Study design, Patient assessment, Demographic data, Data analysis, and result Device failures and replacements: Refer to NAMSA Reports (Attachments 3,4,5).

X. Conclusions Drawn from the Studies, Risk/benefit analysis, Safety Effectiveness: Refer to NAMSA Reports (Attachments 3,4,5) Safety and Performance: Substantial equivalence for this device was based on similarities in design and performance characteristics as well as performance testing. The Materials, performance specifications and essential design characteristics of the PMT Sof-Pach™ electrodes are equivalent to those of predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and in comparison to predicate devices, the PMT Sof-Pach™ electrodes have been shown to be safe and effective for their intended use.

XI. Panel Recommendations
XII. CDRH Decision
XIII. Approval Specifications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2001

Mr. Joshua Lefkovitz
Official Correspondent
Pain Management Technologies, Inc.
43 East Market Street
Akron, Ohio 44308

Re: K011411
Trade Name: Self-Adhesive Electrodes
Regulation Number: 882.1320
Regulatory Class: II
Product Code: GXY
Dated: April 29, 2001
Received: May 8, 2001

Dear Mr. Lefkovitz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhous

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011411

Device Name:_____

Indications For Use:

The PMT electrodes are intended to be used for tens and ems stimulation for pain relief.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011411